UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	
	)	**MDL No. 2419**
	)	**Dkt. No 1:13-md-2419 (RWZ)**
THIS DOCUMENT RELATES TO:	)	
All Cases	)	

Motion to Compel Compliance with Subpoena to the United States Food and Drug Administration

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), hereby move the Court, pursuant to Fed. R. Civ. P. 45, to compel the United States Food and Drug Administration ("FDA") to comply with the subpoena for production of documents and of a Fed. R. Civ. P. 30(b)(6) witness or witnesses. In support of their motion, the Tennessee Clinic Defendants state as follows:

Background

As the Court is well-aware by now, these cases arise from the 2012 fungal meningitis outbreak caused by contaminated medication manufactured by the New England Compounding Center ("NECC"). Following the outbreak, questions arose about whether the FDA could have prevented the outbreak by acting on multiple complaints it received regarding NECC's products.

These questions prompted a Congressional investigation into the FDA's involvement with NECC. Congress required the FDA to produce documents related to its history with NECC, and FDA Commissioner Margaret Hamburg, MD testified before a Congressional committee on November 14, 2012.

One of the results of the investigation was a Congressional report titled, "FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?"[1] The report concluded, among other things, that:

> "One of FDA's fundamental reasons for existence is to protect the public health by assuring the safety of our nation's drug supply. With respect to NECC and Ameridose, documents produced to the Committee raise serious questions about whether FDA repeatedly failed in its core mission. . . .The agency's inaction in the face of years of complaints and red flags associated with the safety of both companies' products and underlying practices had a tragic ending. While nobody could have fully anticipated the scope of this terrible outbreak, FDA was on notice that something like this might occur."[2]

In the Master Complaint, the Plaintiffs allege that the Clinic Defendants should have undertaken certain due diligence prior to purchasing from NECC that would have uncovered the complaints received by the FDA regarding NECC, and prompted the Clinic Defendants to purchase medication elsewhere.

On September 30, 2014, the Tennessee Clinic Defendants filed their Answers to the Master Complaint, asserting comparative fault against the FDA for, *inter alia*, (1) failing to take action against NECC after receiving numerous complaints, and (2) failing to at least warn the public about those complaints.

In order to prove that the complaints received by the FDA regarding NECC were not available to the Tennessee Clinic Defendants and support the assertion of comparative fault against the FDA, these Defendants pursued discovery from the FDA

[1] Attached hereto as Exhibit 1.
[2] Exhibit 1, p. 39.

by (1) accessing documents made available online by the FDA regarding NECC and (2) submitting Freedom of Information Act Requests to the FDA. Next, the Tennessee Clinic Defendants reached out to the FDA numerous times beginning as early as February 2015 to discuss the issuance of the current subpoena.

During discussions with counsel for the Tennessee Clinic Defendants, the FDA's Lead Testimony Specialist for the FDA agreed to accept service of the subpoena on behalf of the FDA. The subpoena was issued on March 6, 2015, for deposition on May 4, 2015.[3]

On March 20, 2015, the FDA objected to the subpoena by letter.[4]

On March 31, 2015, counsel for the Tennessee Clinic Defendants wrote to counsel for the FDA to address the FDA's objections and invite the FDA to meet and confer.[5]

On April 14, 2015, counsel for the FDA and the Tennessee Clinic Defendants met and conferred via phone but were unable to resolve the FDA's objections to the subpoena, necessitating the current motion.[6] The Tennessee Clinic Defendants will continue to meet and confer with the FDA and will update the Court on any resolution to the discovery dispute reached prior to the scheduled hearing.

Law and Argument

This Court has previously recognized the broad scope of discovery. In the Order on Motions to Quash and Objections to Subpoenas,[7] Magistrate Judge Boal echoed the

[3] The "subpoena package" to the FDA, which includes email correspondence to the FDA, the subpoena, the Notice of 30(b)(6) Deposition, and *duces tecum*, is attached as Exhibit 2.
[4] Exhibit 3.
[5] Exhibit 4.
[6] Attached as Exhibit 5 is a letter from the Tennessee Clinic Defendants to the FDA memorializing the call.
[7] Dkt. Entry 572.

Supreme Court's instruction that the limits set forth in Rule 26 must be "construed broadly to encompass any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case."[8]

I. The Testimony and Documents Sought are Relevant and, in fact, Critical to the Tennessee Clinic Defendants' Defense.

The Plaintiffs allege that the Tennessee Clinic Defendants should not have purchased MPA from a compounding pharmacy and specifically should not have purchased MPA from NECC. The Plaintiffs contend that the FDA advised against purchasing from compounding pharmacies prior to the meningitis outbreak. The Plaintiffs also contend that purchasing from an "FDA-regulated" manufacturer of medication would have been *per se* safer than purchasing from a compounder, and that the Tennessee Clinic Defendants should have known that the FDA was not exercising its enforcement power over NECC or other compounding pharmacies.

In their Answers to the Master Complaint, the Tennessee Clinic Defendants assert comparative fault against the FDA for failing to take proper enforcement action against NECC that could have prevented the meningitis outbreak and for failing to warn the public about complaints the FDA received regarding NECC. Similarly, the Tennessee Clinic Defendants assert comparative fault against the Massachusetts Board of Pharmacy. Prior to the meningitis outbreak, the FDA corresponded with the Massachusetts Board of Pharmacy regarding complaints against NECC.[9] The FDA also met with representatives from the Massachusetts Board of Pharmacy to "review the inspectional history of the New England Compounding Center and develop a joint

[8] *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978).
[9] *See* Exhibit 1, p. 20.

strategy for achieving safe compounding practices at the firm."[10] Testimony about the FDA's knowledge of NECC prior to the outbreak, its enforcement actions against NECC, and its coordinated efforts with the Massachusetts Board of Pharmacy are essential for the Tennessee Clinic Defendants to prepare an adequate defense.

The Tennessee Clinic Defendants' deposition testimony demonstrates that they relied on the government to regulate NECC. For example, Dr. Culclasure was asked, "If there were any questions about the quality of steroids at NECC, did you expect Ms. Schamberg to find that out?"[11] Dr. Culclasure responded, "No, I expected the FDA and the Tennessee department of pharmacy and the Massachusetts Board of Pharmacy to be on top of that."[12]

Based on the Plaintiffs' allegations and the FDA's limited production thus far, the requested testimony and documents from the FDA are directly relevant to, and critical for defending, the claims against the Tennessee Clinic Defendants.

II. The Court Should Compel FDA's 30(b)(6) Deposition Testimony.

The Federal Rules explicitly permit a 30(b)(6) deposition of a government agency. Rule 30(b)(6) provides, in pertinent part, that "a party may name as the deponent a public or private corporation, a partnership, an association, **a governmental agency,** or other entity . . . ." (emphasis added). The Federal Rules of Civil Procedure are "as binding as any statute duly enacted by Congress."[13] There is no express or implied exception to Rule 30(b)(6) for agencies.[14]

[10] Exhibit 1, p. 8.
[11] Deposition of John Culclasure, M.D., 121:14-16.
[12] Deposition of John Culclasure, M.D., 121:17-19.
[13] *Bank of Nova Scotia v. United States*, 487 U.S. 250, 255 (1988); 28 U.S.C. § 2072(b).
[14] *See S.E.C. v. Merkin*, 283 F.R.D. 689, 693 *objections overruled*, 283 F.R.D. 699 (S.D. Fla. 2012).

The Advisory Committee Notes to Rule 30(b)(6) reflect that Rule 30(b)(6) was revised in 1970 specifically to allow for the deposition of a governmental agency.[15]

Despite the FDA's contention that most of the information sought by the Tennessee Clinic Defendants is available in Commissioner Hamburg's Congressional testimony, it is clear from the Congressional report that (1) "the FDA produced only a limited number of documents . . . prior to the November 2012 hearing" and (2) the FDA has since produced a substantial number of documents to Congress.[16] Accordingly, it would have been impossible for members of Congress to elicit testimony from Commissioner Hamburg regarding documents that had not yet been produced. It is also clear from the report that many of the documents produced to Congress have not been produced to the Tennessee Clinic Defendants, such as internal FDA communications.

A. FDA's Objections to Testimony

In response to the Tennessee Clinic Defendants' subpoena for 30(b)(6) deposition testimony and production of documents, the FDA objected on multiple grounds. Those objections are addressed below.

1. Statement to the Commissioner

The FDA objected to the request for testimony because the Tennessee Clinic Defendants did not submit a written request directly to Commissioner Hamburg pursuant to 21 C.F.R. § 20.1. However, 21 C.F.R. § 20.1(c) states, in pertinent part:

> "If it is determined by the Commissioner, **or any other officer or employee of the Food and Drug Administration whom he may designate to act on his behalf for the purpose**, that such testimony will be in the public interest and will promote the objectives of the act and the agency, the request may be granted. Where a request for testimony is granted, one or more employees of the Food and Drug Administration may

[15] FED. R. CIV. P. 30.
[16] Exhibit 1. *See* pp. 1-2.

> be designated to appear, in response to a subpoena, and testify with respect thereto." (Emphasis added).

Prior to issuing the subpoena and notice, counsel for the Tennessee Clinic Defendants had multiple conversations, both oral and by email, with Ms. Lauren DiPaola – the FDA's *Senior Testimony Specialist* – to arrange service. Ms. DiPaola instructed counsel to issue the subpoena and deposition notice directly to her. Ms. DiPaola's representations indicated she had been "designated to act on the Commissioner's behalf" for the purpose of receiving and responding to our request for testimony.[17] The FDA cannot invite the subpoena, agree to accept it, and then claim that a proper request was not made under the FDA's housekeeping regulations.

2. 100-mile Limitation Under Rule 45.

On March 6, 2015, the Tennessee Clinic Defendants issued a subpoena and notice to Ms. DiPaola for a 30(b)(6) deposition tentatively scheduled for May 4, 2015 in Nashville, Tennessee. The Tennessee Clinic Defendants made clear to the FDA that the proposed date and location for the deposition were tentative because it was unknown whether an FDA representative from Nashville, Boston, or someplace else would testify.

Only after a government agency receives a notice for a Rule 30(b)(6) deposition does it designate its "officers, directors, or managing agents" to testify on its behalf.[18] Thus, at the time the subpoena and deposition notice were served upon the FDA, it was impossible for the Tennessee Clinic Defendants to know whether the FDA's designee

[17] Furthermore, federal courts have held that to the extent the FDA's regulations conflict with the Federal Rules of Civil Procedure, the regulations are invalid for exceeding the FDA's authority under 5 U.S.C. § 301, the federal "housekeeping" statute. *S.E.C. v. Selden*, 484 F. Supp. 2d 105, 108 (D.D.C. 2007); *Metrex Research Corp. v. United States*, 151 F.R.D. 122, 124 (D. Colo. 1993) ("§20.1 is a regulation promulgated by FDA for its own benefit. It does not supersede the Federal Rules of Civil Procedure").

[18] FED. R. CIV. P. 30(b)(6).

"resides, is employed, or regularly transacts business in person" within 100 miles of Nashville, Tennessee.

Regardless of whether the "person" for purposes of Rules 45 and 30(b)(6) is the FDA as an organization or the actual witness(es) the FDA designates, the Tennessee Clinic Defendants agree to depose the FDA's designee within 100 miles of the FDA's Maryland headquarters or any other mutually agreeable location.

Additionally, in the phone conference on April 14, 2015, the FDA objected to the subpoena because it was issued by the United States District Court for the District of Massachusetts. FDA's counsel asserted that the District of Massachusetts lacks personal jurisdiction over the FDA and that the subpoena should have been issued by the United States District Court for the District of Maryland. Under the weight of federal precedent, this objection must fail.

As the transferee court in this multidistrict litigation, the District Court for the District of Massachusetts clearly has jurisdiction. 28 U.S.C. § 1407(b) expressly empowers an MDL court to "exercise the powers of a district judge in **any** district for the purpose of conducting pretrial depositions[.]" 28 U.S.C. § 1407(b) (emphasis added); *see also U.S. ex rel. Pogue v. Diabetes Treatment Centers of America, Inc.,* 444 F.3d 462, 468-69 (6th Cir. 2006) (describing MDL Court's broad powers over nonparty discovery and noting that "the MDL judge is acting as a judge of the deposition or discovery district when he uses the authority outlined in Section 1407(b)").

Moreover, Magistrate Judge Boal already overruled a similar objection in the Order on Motions to Quash and Objections to Subpoenas.[19]

[19] Dkt. Entry 572.

3. Assertion of Various Privileges

In objection to the subpoena, the FDA asserted numerous privileges, including trade secret, deliberative process privilege, attorney-client privilege, and the work-product doctrine. These objections to *production* do not impact the Tennessee Clinic Defendants' ability to depose the FDA's designee under Rule 30(b)(6). In *SEC v. Kramer,* the United States District Court for the Middle District of Florida noted that it is highly unusual to prohibit the taking of a deposition altogether absent extraordinary circumstances.[20] The *Kramer* court held that the need for protection usually cannot be determined before the examination begins, and that a party could move for a protective order if the need actually arises during a deposition.[21] FDA's counsel may also instruct the witness not to answer questions that call for privileged information.

4. Overbreadth and Burden

The FDA objects to the subpoena on the ground that "it would take many hours of review and preparation for one or more FDA employees to become sufficiently versed" on the topics of the sought testimony.[22] Under federal precedent, this argument fails.

In *Connaught Labs., Inc. v. SmithKline Beecham P.L.C.*, the United States District Court for the District of Delaware ordered the FDA to comply with the defendant's subpoenas over the FDA's objection that requiring its employees to testify would create an undue burden on the FDA.[23] A government agency provided notice

[20] 778 F. Supp. 2d 1320, 1327 (M.D. Fla. 2011).
[21] *Id.* at 1327-28.
[22] As discussed below, the FDA spent two years preparing to indict NECC's principals. The notion that the FDA did not familiarize itself with the NECC documents prior filing the indictment is absurd. Additionally, the bulk of the documents were presumably reviewed before they were produced to Congress years ago.
[23] 7 F. Supp. 2d 477, 480 (D. Del. 1998).

under Rule 30(b)(6) "has the duty to name and produce one or more persons who consent to testify on its behalf as to matters known or reasonably available to the organization."[24] The government must comply with reasonable requests for information even when such requests "will entail significant effort on the part of the United States."[25] Like any litigant, the government must abide by the Federal Rules of Civil Procedure.[26]

Therefore, the Court should compel the FDA to comply with the subpoena for 30(b)(6) deposition testimony.

III. The Court Should Compel the Production of FDA Documents.

The FDA raises similar objections to the production of documents requested by the Tennessee Clinic Defendants, but, again, these objections fail. The FDA should be compelled to produce the documents sought by the subpoena.

A. The Requests for Documents are not Overbroad or Unduly Burdensome.

The FDA's objection to the document requests as overbroad and unduly burdensome is difficult to follow. The FDA argues that because the subpoena covers privileged documents, "the subpoena will require significant time to collect and review potentially-responsive documents for possible production."[27]

As observed by Magistrate Judge Boal at Dkt. 572:

> The party resisting discovery bears the burden of showing that the subpoena imposes an undue burden, and it "cannot rely on a mere assertion that compliance would be burdensome and onerous without showing the manner and extent of the burden and the injurious consequences of insisting upon compliance."[28]

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[24] *United States v. Magnesium Corp. of Am.*, No. 2:01-CV-40DB, 2006 U.S. Dist Lexis 87734 (D. Utah Nov. 27, 2006), at *15-16.
[25] *Id.*
[26] *SEC v. Collins & Aikman Corp.*, 256 F.R.D. 403, 414 (S.D.N.Y. 2009).
[27] Exhibit 3, p. 5.
[28] Dkt. 572 (citing *Sterling Merchandising, Inc. v. Nestle, S.A.*, No. 06-1015(SEC), 2008 WL 1767092, at *2 (D.P.R. Apr. 15, 2008) (quoting 9A Charles Alan Wright & Arthur R. Miller, FEDERAL PRACTICE AND

Here, the FDA has not met its burden. And, the Tennessee Clinic Defendants contend that the FDA *cannot* do so for two reasons. First, Congress initially requested all documents in the FDA's possession related to NECC prior to the November 14, 2012, Congressional hearings regarding the fungal meningitis outbreak.[29] Sometime after the hearing but before the release of the Congressional report in April 2013, the FDA complied with the Congressional request.[30] Accordingly, the FDA has already collected and reviewed most, if not all, of the documents sought by the Tennessee Clinic Defendants' subpoena and can simply reproduce them.

Similarly, the FDA spent approximately two years preparing to indict NECC's owners and employees.[31] The notion that the FDA did not collect and review the NECC documents in its possession prior to filing the indictment is simply not credible. Thus, the bulk of the work necessary to produce these documents has been completed. All that could possibly remain is identification and redaction or removal of privileged material, which may well have been done before the documents were produced to Congress.

B. The Existence of *Some* Privileged Documents does not Justify Refusing to Produce *Any* Documents.

Next, the FDA objects to the document requests in the subpoena because they may cover documents that contain information covered by various privileges. If

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PROCEDURE § 2459 (2d ed. 1995)); see also *Ameritox, Ltd. v. Millennium Labs., Inc.*, No. 12-cv-7493, 2012 WL 6568226, at *2 (N.D. Ill. Dec. 14, 2012) ("To demonstrate undue burden, the movant must provide 'affirmative and compelling proof.'"); *Biological Processors of Alabama, Inc. v. North Georgia Environmental Servs., Inc.*, No. 09-3673, 2009 WL 1663102, at *1 (E.D. La. June 11, 2009) (citation omitted) ("When the burdensomeness of a subpoena is at issue, the onus is on the party who alleges the burden to establish the burden with specificity, 'and assertions of a burden without specific estimates of staff hours needed to comply' are typically rejected.").

[29] *See* Exhibit 1, p. 1-2.

[30] *Id.*

[31] http://www.justice.gov/opa/pr/14-indicted-connection-new-england-compounding-center-and-nationwide-fungal-meningitis.

privileged documents exist, the FDA can simply identify them on a privilege log as contemplated by Fed. R. Civ. P. 45(e)(2).

The also FDA contends that it cannot produce trade secrets or proprietary information without (1) a protective order in place or (2) permission from the entity to which the trade secret belongs. However, there *is* a protective order in place. And, the FDA fails to identify whose trade secrets or proprietary business information it is protecting, preventing the Tennessee Clinic Defendants from obtaining the necessary permission. The FDA should be compelled to produce the documents or at least identify to whom the trade secrets belong.

C. The Time Provided for Compliance is Reasonable.

Finally, the FDA objects to the subpoena on the grounds that compliance by May 4, 2015, is not a reasonable amount of time for compliance. As Magistrate Judge Boal has already observed in this litigation:

> "Although Rule 45 does not define 'reasonable time,' many courts have found fourteen days from the date of service as presumptively reasonable.[32]"

As noted above, the work necessary to collect and review these documents should be complete, and nearly 60 days is hardly an unreasonable amount of time to complete any privilege review that is not already complete. The Tennessee Clinic Defendants have offered to work with the FDA on a mutually-agreeable date prior to the current mid-June discovery deadline. The FDA has not yet given the Tennessee Clinic Defendants an estimate on how much time production will take.

[32] Dkt. 572 (citing *Brown v. Hendler,* No. 09 Civ. 4486 (RLE), 2011 WL 321139, at *2 (S.D.N.Y. Jan. 31, 2011) (nine days not reasonable); *Cris v. Fareri*, No. 3:10CV1926, 2011 WL 4433961, at *2 (D. Conn. Sept. 22, 2011); *McClendon v. Telohio Credit Union, Inc.*, No. 2:05-cv-1160, 2006 WL 2380601, at *2 (S.D. Ohio Aug. 14, 2006)).

Conclusion

For the foregoing reasons, the Court should grant the Tennessee Clinic Defendants' Motion to Compel and order the FDA to produce a 30(b)(6) witness for deposition testimony and produce the requested documents.

Oral Argument Requested

The Tennessee Clinic Defendants request oral argument on this motion at the hearing before Magistrate Judge Boal on April 29, 2015, at 11:30 am EDT in Courtroom 14.[33]

Respectfully submitted,

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[33] The Tennessee Clinic Defendants believe that this motion has been referred to Magistrate Judge Boal pursuant to Dkt. 1708, which referred all "discovery motions" to Magistrate Judge Boal. If this motion is not referred to Magistrate Judge Boal, the Tennessee Clinic Defendants request oral argument at the status conference before Judge Zobel on April 29, 2015, at 2:00 pm EDT in Courtroom 12.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 14th day of April, 2015.

/s/ Chris J. Tardio
Chris J. Tardio